

**SUMMARY OF PUBLIC COMMENTS RECEIVED ON THE GOVERNMENT
OF CANADA'S ECOLOGICAL SCREENING ASSESSMENT OF
PERFLUOROOCTANE SULFONATE (PFOS), ITS SALTS, AND ITS
PRECURSORS (COMPOUNDS THAT CONTAIN ONE OF THE FOLLOWING
GROUPS: C₈F₁₇SO₂, C₈F₁₇SO₃ OR C₈F₁₇SO₂N)**

An announcement of draft ecological and human health screening assessment reports on *Perfluorooctane Sulfonate (PFOS), its Salts, and its Precursors* was published in the *Canada Gazette* on October 2, 2004. On December 2, 2004, the stipulated 60-day public comment period ended. Comments were submitted by non-governmental organizations (NGOs)¹, academia², industry³, and one member of the public⁴. Comments covered the following topics: general comments on the assessment process and timeframe, physico-chemical properties, precursors, exposure in water and wildlife, effects in aquatic biota, birds and wildlife, effects in the atmosphere, bioaccumulation and bioconcentration, cumulative risk assessments, conservatism and application factors, weight of evidence, and plans for risk management.

Comments from the Non-Governmental Organizations and Member of the Public

The NGOs supported Environment Canada's conclusion of PFOS as meeting the criterion set out under paragraph 64 (a) of CEPA 1999 and the recommendations to virtually eliminate PFOS as required under section 65(3). However, the NGOs and one member of the public had the following concerns:

- information presented in the draft ecological screening assessment report to allow for a determination under CEPA s.64(a)
 - Because NGOs assumed that the determination of persistence, bioaccumulation, and inherent toxicity formed the basis for the decision of meeting the criterion set out under paragraph 64(a) of CEPA 1999, further information was requested.
- timeframe of the ecological screening assessment process
 - The draft PFOS ecological screening assessment required four years to complete, therefore, concerns were expressed that similar time delays would inhibit accountability and transparency of future assessments.
 - Health Canada and Environment Canada were recommended to jointly design guidelines, timetables, and criteria to outline timelines for screening level risk assessments and specify the conditions for a comprehensive risk assessment (i.e. Priority Substance List).
- cumulative effects from exposure to multiple chemicals

¹ Canadian Environmental Law Association, Learning Disabilities Association of Canada, Le Comité de la Protection de la Santé et de l'Environnement de Gaspé Inc (Québec), The Allergy and Environmental Illness Group (PEI), Canadian Association of Physicians for the Environment (Ontario), Canadian Institute for Environmental Law and Policy (Ontario), Citizens' Network on Waste Management (Ontario), Edmonton Friends of the North Environmental Society (Alberta), Georgia Strait Alliance (British Columbia), Great Lakes United, Nature Saskatchewan (Saskatchewan), Ontario Toxic Waste Research Coalition (Ontario), STORM Coalition (Ontario), Saint John Citizens Coalition for Clean Air (New Brunswick), Sierra Club of Canada (Ontario), Toxics Watch Society (Alberta)

² Michigan State University (USA)

³ 3M Canada Company and Industry Coordinating Group for CEPA

⁴ Independent Toxicologist (USA)

- It was stated that both Health Canada and Environment Canada have avoided addressing cumulative effects. For example, the additive effects from exposure to other perfluorinated compounds given their structural similarities with PFOS, their co-occurrence in products/humans/environment and their similarities in the mechanism of bioaccumulation, mode of action, and toxic effects were not considered.
- risk management of PFOS, its salts, and its precursors
 - It was suggested that the risk assessment process in Canada should align with the United Kingdom and European Union and proceed to a Risk Reduction Strategy on the basis of weight of evidence for persistence, bioaccumulation, and toxic.

Comments from Academia

There was agreement with the conclusion that PFOS is persistent in water, air, soil, and sediments, that PFOS is bioaccumulative and that it was appropriate to consider all compounds in the PFOS-containing class when conceptualizing a risk assessment. However, critiques were provided on the following topics:

- The characterization of PFOS toxicity data to aquatic biota ought to suggest that PFOS has minimal toxicity to aquatic life.
- The characterization of the hazard and risk for the avian and wildlife effects was inappropriate through the use of single maximum concentrations, the use of non-Canadian environmental concentrations was not appropriate and the use of a 10 fold safety factor for a bioaccumulative substance was excessive.
- The information presented was a '*preponderance of evidence*' approach instead of a line of evidence approach.
- The CATABOL model was judged invalid for perfluorinated compounds as the model was not validated for these compounds and, therefore, it was inappropriate to conclude all precursors identified in the assessment will degrade to PFOS.

Comments from Industry

Industry provided comments with implications on policy or process, including Environment Canada's risk management strategy of virtual elimination to which industry proposed alternatives (i.e., the Significant New Activity Rule s.87 of CEPA or the European Union track of Risk Reduction Strategies). Other policy or process comments included:

- It was stated that industry comments submitted under the 2003 external peer review process were not reflected and there was the implication that the listed peer reviewers endorsed the draft ecological screening assessment.
- There was criticism over Environment Canada's use of an external contractor for the preparation of the draft ecological screening assessment and the perceived failure to adhere with Environment Canada's guidance documents and statutory mandate to consider weight of evidence.
- It was stated that the weight of evidence did not support a conclusion of meeting the criterion set out under paragraph 64 (a) of CEPA 1999.

Industry also provided technical comments which addressed issues such as:

- the lack of a complete/scientifically sound characterization of the physical-chemical properties of PFOS given the available data,
- the inappropriate selection and use of endpoints,
- the inappropriate use of application factors and environmental concentrations in risk quotient calculations for mammalian, avian, aquatic and surface water components and:
- the use of inappropriate bioaccumulation data which overestimated the bioaccumulation potential.

Environment Canada's Approach and Response to the Public Comments

All comments from the 60-day public comment period were carefully tabulated, reviewed, and addressed. The following presents a brief description of the approach taken and response to the topics outlined above:

- The purpose of the ecological assessment report is to describe the critical and valid information and the weight of evidence which is used to determine whether a substance meets the criteria of section 64 of the *Canadian Environmental Protection Act, 1999*. Specifically, "a substance is toxic if it is entering or may enter the environment in a quantity or concentration or under conditions that have or may have an immediate or long term harmful effect on the environment or its biological diversity or if it constitutes or may constitute a danger to the environment on which life depends or a danger in Canada to human life or health".
- Environment Canada had retained a consultant to prepare an initial critical review of issues pertaining to the properties, environmental fate, and effects of PFOS and its precursors. However, Environment Canada scientists drafted the ecological screening assessment, based only partially on information in the consultant's review. In addition, Environment Canada's draft assessment underwent both an internal and external science review. This included national and international experts in government, academia, and industry.
- Questions related to policy issues (e.g., timeframe) and assessment process will be addressed separately as part of post-categorization discussions.
- The assessment approaches described in Environment Canada's guidance documents are intended as general guidance which can be adapted as appropriate. In addition, all assessments undergo internal and external reviews to ensure appropriateness of assessment approaches. Comments received from the 2003 external science peer review process and the 2004 public comment process for the PFOS draft ecological assessment were carefully considered and incorporated into the assessment where appropriate. It has now been noted in the revised ecological screening assessment report that the conclusion does not necessarily reflect the opinion of the peer reviewers.
- Given that precursors to PFOS may contribute to the total loading of PFOS in the environment, precursors were assessed together with PFOS. The assessment identified more than 50 precursors to PFOS based on CATABOL modeling and

expert judgment. The CATABOL model used to predict precursors degrading to PFOS were based on limited empirical data. However, all empirical information available supports the predictions generated. Thus, the assessment made recommendations for PFOS, its salts, and its precursors.

- New literature published between February 2004 and August 2005, conference presentations (e.g., International Symposium on Fluorinated Alkyl Organics in the Environment 2005, Dioxins 2004, SETAC 2004), together with critical data in the draft screening ecological assessment were reviewed for acceptability, relevance, and inclusion in the assessment. More Canadian-related information was obtained during this period and, where appropriate, used in the final assessment. The ecological screening assessment does not present an exhaustive summary of all the available data. Rather, it presents the most critical studies in a weight of evidence approach to support the conclusion. The ecological screening assessment for PFOS has been revised to reflect the weight of evidence for PFOS with respect to persistence, bioaccumulation, the widespread occurrence of and concentrations of PFOS in the environment and in biota (including remote areas of Canada), risk quotients reflecting a range of exposure conditions, trends, and transformation or degradation to PFOS (precursors).
- The risk quotient analyses for birds, mammals (i.e. polar bear), and aquatic species have been revised based on new studies, and multiple concentration and endpoint data. For aquatic toxicity, acceptable studies were analyzed using two methods to derive risk quotients: species sensitivity distribution using the 5th percentile of the range of effects concentrations for various species and a single conservative effects estimate. In addition, exposure was evaluated in two ways: using a maximal exposure concentration and using a range of values representing exposure conditions in various locations. It should be noted that these methods gave consistent results. The application factor of 10 for persistent and bioaccumulative substances has been removed from the risk quotient calculations.
- Environment Canada organized and hosted a Workshop on the Bioaccumulation of Perfluorinated Substances (August 2005) attended by 25 international scientific experts to discuss available information and knowledge gaps relating to the issue of bioaccumulation, bioconcentration, and biomagnification of certain perfluorinated substances, including PFOS, and to identify appropriate alternative approaches for characterizing or predicting biological fate for these substances. PFOS is concluded to be a bioaccumulative substance taking into account the intrinsic properties of the substance, the ecosystem under consideration, the conditions in the environment, and both field and laboratory-derived whole body and tissue-specific bioconcentration factors, bioaccumulation factors, and biomagnification factors.
- A Risk Management Strategy for PFOS, its salts, and its precursors is being prepared and consultations will be held with affected stakeholders following publication of the final ecological screening assessment report in 2006.